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SEP 11 2008



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USAPhone Calls: 301-881-0666
8 a.m. to 5 p.m. EST Mon. - Fri.**ATTENTION !**

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

METHACRYLIC ACID COPOLYMER, TYPE A

Catalog Number: 1396400

Revision Date: April 29, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Methacrylic Acid Copolymer, Type A

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Methacrylic Acid Copolymer, Type A

Formula: (C₅H₈O₂)_x, (C₄H₆O₂)_y

Synonym: Acrylic copolymer

Chemical Name: Methacrylic Acid Copolymer, Type A

CAS: 25086-15-1

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n/f = not found

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METHACRYLIC ACID COPOLYMER, TYPE A

Catalog Number: 1396400

Revision Date:

April 29, 2005

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutic aid (tablet coating agent)

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES**Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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METHACRYLIC ACID COPOLYMER, TYPE A

Catalog Number: 1396400

Revision Date:

April 29, 2005

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; weak to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >482° F (COC)

Autoignition Temperature: >400° C

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1

Specific Gravity: n/f

Solubility in Water: Insoluble

Fat Solubility: n/f

Other Solubility: n/f

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: (C₅H₈O₂)_x, (C₄H₆O₂)_y

Molecular Weight: Approximately 135,000

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METHACRYLIC ACID COPOLYMER, TYPE A

Catalog Number: 1396400

Revision Date:

April 29, 2005

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid heat.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization? No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: >5000 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

SECTION 16 - OTHER INFORMATION

Revision: 29-Apr-05

Previous Revision Date: 21-Nov-01

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METHACRYLIC ACID COPOLYMER, TYPE B

Catalog Number: 1396502

Revision Date: October 23, 2007

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION**Common Name:** Methacrylic Acid Copolymer, Type B**Manufacturer:** U. S. Pharmacopeia**Responsible Party:** Reference Standards Technical Services**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA**Phone:** 301-816-8129**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.**SECTION 2 - HAZARD INFORMATION****Adverse Effects:** Possible allergic reaction to material if inhaled, ingested or in contact with skin.**Overdose Effects:** n/f**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.**Chronic:** Possible hypersensitization.**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material.**Cross Sensitivity:** n/f**Target Organs:** n/f**For additional information on toxicity, see Section 11.****SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS****Common Name:** Methacrylic Acid Copolymer, Type B**Formula:** (C₅H₈O₂)_x, (C₄H₆O₂)_y**Synonym:** Acrylic copolymer**Chemical Name:** Methacrylic Acid Copolymer, Type B**CAS:** 25086-15-1

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METHACRYLIC ACID COPOLYMER, TYPE B

Catalog Number: 1396502

Revision Date:

October 23, 2007

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutic aid (tablet coating agent)

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES**Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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METHACRYLIC ACID COPOLYMER, TYPE B

Catalog Number: 1396502

Revision Date:

October 23, 2007

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; weak to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >482° F (COC)

Autoignition Temperature: n/f

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1 (Air=1)

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Soluble in methanol and in ethanol; practically insoluble in ethyl acetate, in methylene chloride, and in petroleum ether

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: (C₅H₈O₂)_x, (C₄H₆O₂)_y

Molecular Weight: Approximately 135,000

METHACRYLIC ACID COPOLYMER, TYPE B

Catalog Number: 1396502

Revision Date:

October 23, 2007

SECTION 10 - STABILITY AND REACTIVITY**Conditions to Avoid:** Avoid heat.**Incompatibilities:** n/f**Decomposition Products:** When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.**Stable?** Yes **Hazardous Polymerization?** No**SECTION 11 - TOXICOLOGICAL PROPERTIES****Oral Rat:** LD50: >5000 mg/kg**Oral Mouse:** LD50: n/f**Other Toxicity Data:** Oral Dog: LD50: >10 grams/kg**Irritancy Data:** n/f**Corrosivity:** n/f**Sensitization Data:** n/f**Listed as a Carcinogen by:** **NTP:** No **IARC:** No **OSHA:** No**Other Carcinogenicity Data:** n/f**Mutagenicity Data:** n/f**Reproductive and Developmental Effects:** n/f**SECTION 12 - ECOLOGICAL INFORMATION****Ecological Information:** n/f**SECTION 13 - DISPOSAL CONSIDERATIONS****Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.**SECTION 14 - TRANSPORT INFORMATION****Shipping Name:** n/f**Class:** n/f**UN Number:** n/f**Packing Group:** n/f**Additional Transport Information:** n/f**SECTION 15 - REGULATORY INFORMATION****U.S. Regulatory Information:** n/f**International Regulatory Information:** n/f**SECTION 16 - OTHER INFORMATION****Revision:** 23-Oct-07**Previous Revision Date:** 29-Apr-05



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METHACRYLIC ACID COPOLYMER, TYPE C

Catalog Number: 1396604

Revision Date: April 29, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Methacrylic Acid Copolymer, Type C

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

Adverse Effects: Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Methacrylic Acid Copolymer, Type C

Formula: n/f

Synonym: Acrylic copolymer

Chemical Name: Methacrylic Acid Copolymer, Type C

CAS: 25086-15-1

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METHACRYLIC ACID COPOLYMER, TYPE C

Catalog Number: 1396604

Revision Date:

April 29, 2005

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutic aid (tablet coating agent)

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES**Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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METHACRYLIC ACID COPOLYMER, TYPE C

Catalog Number: 1396604

Revision Date:

April 29, 2005

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; faint to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >250° C (COC)

Autoignition Temperature: >400° C

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1

Specific Gravity: n/f

Solubility in Water: Insoluble

Fat Solubility: n/f

Other Solubility: Soluble in aqueous alkalies, in acetone, and in lower alcohols.

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: n/f

Molecular Weight: Approximately 135,000

METHACRYLIC ACID COPOLYMER, TYPE C

Catalog Number: 1396604

Revision Date:

April 29, 2005

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization? No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: >5000 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: Oral dog: LD50: >5000 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packaging Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

SECTION 16 - OTHER INFORMATION

Revision: 29-Apr-05

Previous Revision Date: 21-Nov-01

JP XIV

Official Monographs for Part II / Cellulose Acetate Phthalate 893

a previously dried and tared evaporation dish. The difference between the mass of the residue and the mass obtained from a blank determination does not exceed 15.0 mg.

(3) Heavy metals—Proceed with 2.0 g of Powdered Cellulose according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard lead Solution (not more than 10 ppm).

Loss on drying Not more than 6.0% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.3% (1 g calculated on the dried basis, the addition of sulfuric acid being omitted from the procedure).

Microbial limits The total aerobic microbial count does not exceed 1000 per g, the total combined fungus and yeast count does not exceed 100 per g, and *Escherichia coli*, *Salmonella* species, *Staphylococcus aureus* and *Pseudomonas aeruginosa* are not observed.

Containers and storage Containers—Tight containers.

Cellulose Acetate Phthalate

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Cellulose acetate benzene-1,2-dicarboxylate
(9004-38-0)

Cellulose Acetate Phthalate is a reaction product of phthalic anhydride and partially acetylated cellulose.

Cellulose Acetate Phthalate, calculated on the anhydrous and free acid-free basis, contains not less than 21.5% and not more than 26.0% of acetyl group ($-\text{COCH}_3$: 43.05), and not less than 30.0% and not more than 40.0% of carboxybenzoyl group ($-\text{COC}_6\text{H}_4\text{COOH}$: 149.13).

Description Cellulose Acetate Phthalate occurs as a white powder or grain. It is odorless or has a faint, acetous odor.

It is freely soluble in acetone, and practically insoluble in water, in methanol, in ethanol (95) and in dichloromethane.

Identification (1) Determine the infrared absorption spectrum of Cellulose Acetate Phthalate as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or spectrum of Cellulose Acetate Phthalate Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) Dissolve 150 mg of Cellulose Acetate Phthalate in 1 mL of acetone, and pour on a surface of a transparent glass plate in a well-ventilated place: a lustrous transparent film is formed after evaporating of the acetone.

Viscosity Weigh accurately a quantity of Cellulose Acetate Phthalate, equivalent to 15 g calculated on the anhydrous basis, dissolve in 85 g of a mixture of acetone and water (249: 1 in mass), and perform the test with this solution at $25 \pm 0.2^\circ\text{C}$ as directed in Method 1 under the Viscosity Determination to obtain the kinematic viscosity ν . Separately, determine the density, ρ , of Cellulose Acetate Phthalate as directed under the Determination of Specific Gravity and Density,

and calculate the viscosity, η , as $\eta = \rho\nu$: not less than 45 mPa·s and not more than 90 mPa·s.

Purity (1) Heavy metals—Proceed with 2.0 g of Cellulose Acetate Phthalate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Free acids—Weigh accurately about 3.0 g of Cellulose Acetate Phthalate, put in a glass-stoppered conical flask, add 100 mL of diluted methanol (1 in 2), stopper tightly, and filter after shaking for 2 hours. Wash both the flask and residue with two 10-mL portions each of diluted methanol (1 in 2), combine the washes to the filtrate, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform the blank determination with 120 mL of diluted methanol (1 in 2), and make any necessary correction.

$$\text{Amount (\% of free acids)} = \frac{0.8306 \times A}{W}$$

A: amount (mL) of 0.1 mol/L sodium hydroxide consumed

W: amount (g) of the test sample, calculated on the anhydrous basis

The amount of free acids is not more than 3.0%, calculated as phthalic acid ($\text{C}_8\text{H}_6\text{O}_4$: 166.13).

Water Not more than 5.0% (1 g, direct titration, using a mixture of dehydrated methanol and dichloromethane (3:2) instead of methanol for Karl Fischer method).

Residue on ignition Not more than 0.1% (1 g).

Assay (1) Carboxybenzoyl group—Weigh accurately about 1 g of Cellulose Acetate Phthalate, dissolve in 50 mL of a mixture of ethanol (95) and acetone (3: 2), and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination, and make any necessary correction.

Content (%) of carboxybenzoyl group ($\text{C}_8\text{H}_5\text{O}_3$)

$$= \frac{\frac{1.491 \times A}{W} - 1.795 \times B}{100 - B} \times 100$$

A: amount (mL) of 0.1 mol/L sodium hydroxide consumed

B: amount (%) of free acids obtained in Purity (2) Free acids

W: amount (g) of the test sample, calculated on the anhydrous basis

(2) Acetyl group—Weigh accurately about 500 mg of Cellulose Acetate Phthalate, put in a glass-stoppered conical flask, add 50 mL of water and exactly 50 mL of 0.5 mol/L sodium hydroxide VS, and boil for 60 minutes under a reflux condenser. After cooling, add 5 drops of phenolphthalein TS, and titrate with 0.5 mol/L hydrochloric acid VS. Perform a blank determination, and make any necessary correction.

Content (%) of free acids and bound acetyl group ($\text{C}_8\text{H}_5\text{O}$)

$$= \frac{2.152 \times A}{W}$$

894 Cetanol / Official Monographs for Part II

JP XIV

A: amount (mL) of 0.5 mol/L sodium hydroxide consumed

W: amount (g) of the test sample, calculated on the anhydrous basis

$$\text{Content (\% of acetyl group (C}_2\text{H}_3\text{O))} \\ = \frac{100 \times (P - 0.5182 \times B)}{100 - B} \times -0.5772 \times C$$

B: amount (%) of free acids obtained in Purity (2) Free acids

C: content (%) of carboxybenzoyl group

P: content (%) of free acids and bound acetyl group (C₂H₃O)

Containers and storage Containers—Tight containers.

Cetanol

セタノール

Cetanol is a mixture of solid alcohols, and consists chiefly of C₁₆H₃₄O.

Description Cetanol occurs as unctuous, white flakes, granules, or masses. It has a faint, characteristic odor. It is tasteless.

It is very soluble in pyridine, freely soluble in ethanol (95), in ethanol (99.5) and in diethyl ether, very slightly soluble in acetic anhydride, and practically insoluble in water.

Melting point 47–53°C Prepare the sample according to Method 2, then attach tightly a capillary tube to the bottom of the thermometer by means of a rubber band or by any suitable means, and make the bottom of the capillary tube equal in position to the lower end of the thermometer. Insert this thermometer into a test tube 17 mm in inside diameter and about 170 mm in height, fasten the thermometer with cork stopper so that the lower end of the thermometer is about 25 mm distant from the bottom of the test tube. Suspend the test tube in a beaker containing water, and heat the beaker with constant stirring until the temperature rises to 5°C below the expected melting point. Then regulate the rate of increase to 1°C per minute. The temperature at which the sample is transparent and no turbidity is produced is taken as the melting point.

Acid value Not more than 1.0.

Ester value Not more than 2.0.

Hydroxyl value 210–232

Iodine value Not more than 2.0.

Purity (1) Clarity of solution—Dissolve 3.0 g of Cetanol in 25 mL of ethanol (99.5) by warming; the solution is clear.

(2) Alkali—To the solution obtained in (1) add 2 drops of phenolphthalein TS; no red color develops.

Residue on ignition Not more than 0.05% (2 g).

Containers and storage Containers—Well-closed containers.

Chlorinated Lime

サラン粉

Chlorinated Lime contains not less than 30.0% of available chlorine (Cl: 35.45).

Description Chlorinated Lime occurs as a white powder. It has a chlorine-like odor.

It dissolves partially in water. The solution changes red litmus paper to blue, then gradually decolorizes.

Identification (1) To Chlorinated Lime add dilute hydrochloric acid; a gas, which has the odor of chlorine, evolves, and the gas changes moistened starch-potassium iodide paper to blue.

(2) Shake 1 g of Chlorinated Lime with 10 mL of water, and filter: the filtrate responds to the Qualitative Tests (2) and (3) for calcium salt.

Assay Weigh accurately about 5 g of Chlorinated Lime, transfer to a mortar, and triturate thoroughly with 50 mL of water. Transfer to a 500-mL volumetric flask with the aid of water, and add water to make 500 mL. Mix well, immediately take exactly 50 mL of the mixture in an iodine flask, add 10 mL of potassium iodide TS and 10 mL of dilute hydrochloric acid, and titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS). Perform a blank determination, and make any necessary correction.

$$\text{Each mL of 0.1 mol/L sodium thiosulfate VS} \\ = 3.5453 \text{ mg of Cl}$$

Containers and storage Containers—Tight containers.

Storage—Light-resistant, and in a cold place.

Chlorobutanol

クロロブタノール



C₄H₇Cl₃O: 177.46

1,1,1-Trichloro-2-methylpropan-2-ol [57-15-8]

Chlorobutanol contains not less than 98.0% of C₄H₇Cl₃O, calculated on the anhydrous basis.

Description Chlorobutanol occurs as colorless or white crystals. It has a camphoraceous odor.

It is very soluble in methanol, in ethanol (95) and in diethyl ether, and slightly soluble in water.

It slowly volatilizes in air.

Melting point: not lower than about 76°C.

Identification (1) To 5 mL of a solution of Chlorobutanol (1 in 200) add 1 mL of sodium hydroxide TS, then slowly add 3 mL of iodine TS: a yellow precipitate is produced and the odor of iodoform is perceptible.



Material Safety Data Sheet

12601 Twinbrook Parkway
Rockville, MD 20852 USA

Telephone calls: (301) 881-0666
8:00am - 5:00pm EST Mon. - Fri.

Responsible Party: Reference Standards Technical Services

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SODIUM BICARBONATE

Catalog Number: 1613655

Package Size: 3 g

Revision Date:

May 18, 2004

EMERGENCY OVERVIEW - Irritant.

SECTION 1 - IDENTIFICATION

Common Name: Sodium Bicarbonate

Formula: NaHCO₃

Synonym: n/f

Chemical Name: Carbonic acid monosodium salt

CAS Number: 144-55-8

RTECS Number: VZ0950000

Chemical Family: n/f

Therapeutic Category: Replenisher (electrolyte), alkalizer (systemic)

SECTION 2 - INGREDIENT INFORMATION

Principle Components

Percent

Exposure Limits

Sodium bicarbonate

Pure Material

n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual adult oral dose is 320 mg to 2 grams one to four times a day, up to 16 grams daily.

Adverse Effects: Adverse effects from ingestion of sodium bicarbonate may include stomach cramps, belching, flatulence, and increased thirst. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Ingestion of extremely large amounts may cause gastrointestinal disturbances and swelling of feet or legs, and may lead to hypokalemia and metabolic alkalosis, symptoms of which may include mood changes; tiredness; shortness of breath; muscle weakness, tension, twitching, and cramping; and irregular heartbeat.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

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Chronic: Possible hypersensitization and hypercalcemia, symptoms of which may include frequent urge to urinate, headache, loss of appetite, nausea, vomiting, and unusual tiredness or weakness.

Inhalation: May cause irritation. Remove to fresh air.

Eye: Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: Causes irritation. Avoid contact. Flush with copious quantities of soap and water.

Ingestion: May cause irritation. Flush out mouth with water.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, metabolic or respiratory alkalosis, hypocalcemia, hypochlorhydria, heart failure, edema, kidney or liver impairment, hypertension, eclampsia, aldosteronism, appendicitis (or symptoms of), and gastrointestinal or rectal bleeding.

Cross Sensitivity: n/f

Pregnancy Comments: Problems in humans have not been documented; however, chronic therapeutic use may lead to system alkalosis, and the sodium that is absorbed may cause accumulation of fluid in tissues and weight gain.

Pregnancy Category: C

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment for overdose of sodium bicarbonate should be symptomatic and supportive and may include the following:

1. Hydrate with 0.9% sodium chloride administered intravenously.
2. For hypokalemia: Administer potassium chloride.
3. For hypocalcemia: Administer calcium gluconate.
4. For severe alkalosis: Administer ammonium chloride or hydrochloric acid; hemodialysis may also be useful. [USP DI 2004]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 4220 mg/kg

Oral Mouse: LD50: 3360 mg/kg

Irritancy Data: RTECS-Human/Skin: mild; Rabbit/Eye: mild

Target Organ(s): n/f

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f **Upper Flammable Limit:** n/f

Auto-Ignition Temperature: n/f **Lower Flammable Limit:** n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is noncombustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to heat and moisture.

Incompatibilities: Monoammonium phosphate, sodium-potassium alloy, and acids.

Decomposition Products: When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labelled container for disposal. Wash spill site.

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

Ventilation: No special ventilation requirements.

Gloves: Rubber

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor:	White crystalline powder; odorless.	
Melting Point:	60° C	
Solubility in Water:	Soluble	Vapor Density: n/f
Boiling Point:	n/f	Evaporation Rate: n/f
Specific Gravity:	2.2	Reactivity in Water: n/f
Vapor Pressure:	n/f	% Volatile by Volume: 0